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10/800,043

03/11/2004

Gary Opperman

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EXAMINER

HILL, KEVIN KAI

ART UNIT

PAPER NUMBER

1633

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/800,043

Applicant(s)

OPPERMAN ET AL.

Examiner

Kevin K. Hill, Ph.D.

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) 3-6, 22-41 and 46-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,7-21 and 42-45 is/are rejected.
- 7) ☒ Claim(s) 9 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :Jul 6, 2004, Aug 11, 2005 and Sep 11, 2005.

Detailed Action

1. Applicant's response to the Requirement for Restriction, filed on November 16, 2006 is acknowledged.

Applicant has elected the invention of Group I, Claims 1-21 and 42-45, drawn to a composition comprising a compound suitable for being immobilized on support and an organic anion of Formula I: $R(X)_m(Y)_n$, and a method of forming spots of said compound on a surface. Claims 22-41 and 46-53 are pending but withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention, there being no allowable generic or linking claim.

Within Group I, Applicant has further elected the restricted subgroup structure "b" of the organic anion of Formula I: $R(X)_m(Y)_n$, wherein the anion has the Formula III, as recited in Claims 7-8 and 19-20. Claims 4-6 are pending but withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention, there being no allowable generic or linking claim.

Within Group I, Applicant has elected the following species:

R = alkyl

m = 6

X = phosphate

n = 0

Y: not applicable because n=0

Z = -OPO₃-

A = -CFI-OPO₃.

Within Group I, Applicant has elected the organic anion composition to be phytate, as recited in Claims 8 and 20.

2. Election of Applicant's invention(s) was made without traverse. However, the species elections are traversed. Applicant argues that a search of both formulas and all possible moiety variable would not present a serious search burden.

Applicants' arguments have been fully considered but are not found persuasive. MPEP §803 states that "If the search and examination of all the claims in an application can be made without serious burden, the examiner must examine them on the merits, even though they include claims to independent or distinct inventions."

In the instant case a serious burden exists since each limitation, directed to a formula, a terminal group, or specific molecule, requires a separate, divergent, and non co-extensive search and examination of the patent and non-patent literature. For instance, a search and consideration of the prior art as it relates to phytate would not be adequate to uncover prior art related to glucose-1-phosphate.

Further, a search and examination of all the claims directed to both embodiments involves different considerations of novelty, obviousness, written description, and enablement for each claim. In view of these requirements, it is the Examiner's position that searching and examining all of the claims including limitations to one or more chemical structures, and all possible variations thereof, in the same application presents a serious burden on the Examiner for the reasons given above and in the previous Restriction Requirement.

The requirement is still deemed proper and is therefore made FINAL.

Amendments

Applicants' amendments to the claims, in the reply filed November 16, 2006, is acknowledged. Also acknowledged are Applicants' new claims, 54-62, which have been entered into the application as requested and will be examined on the merits herein, as they are considered to belong to the elected group, Group I.

It is noted that the original Claims 7 and 19 recited the structure of Formula III, which is disclosed in the specification as Formula IV (pg 9). Applicants have elected "Formula III" for examination purposes and have amended Claims 7 and 19 to be concordant with the structure of Formula III as disclosed in the specification (pg 8). The newly added claims, Claims 55 and 58 iterate the original Claims 7 and 19, reciting a structure of Formula III; however, this structure is disclosed as Formula IV in the specification (pg 9). For the purposes of examination, the

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structure of Formula III, as recited in the amended Claims 7 and 19, and as disclosed in the specification (pg 8) will be examined as the elected structure. Claims drawn to the structure of Formula IV are pending but withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention, there being no allowable generic or linking claim.

3. Claims 3-6, 22-41 and 46-62 are pending but withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention, there being no allowable generic or linking claim.

4. Claims 1-2, 7-21 and 42-45 are under consideration.

Priority

5. Applicant makes no claim for benefit or priority of a prior-filed application. Accordingly, the effective priority date of the instant application is granted as the filing date of the instant application, March 11, 2004.

If applicant believes the earlier applications provide support for this disclosure, applicant should point out such support by page and line number in the reply to this Action.

Information Disclosure Statement

Applicant has filed Information Disclosure Statements on July 6, 2004, August 11, 2005 and September 11, 2005. The signed and initialed PTO Forms 1449 have been mailed with this action.

Specification

The specification is objected to because the use of improperly demarcated trademarks has been noted in this application. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to

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prevent their use in any manner that might adversely affect their validity as trademarks. See MPEP §608.01(v).

An example of such an improperly demarcated trademark is “Tween 20”, which appears in the present specification at page 11, line 21.

Appropriate correction is required. Each letter of a trademark should be capitalized or otherwise the trademark should be demarcated with the appropriate symbol indicating its proprietary nature (e.g. TM, ®), and accompanied by generic terminology. Applicants may identify trademarks using the “Trademark” search engine under “USPTO Search Collections” on the Internet at <http://www.uspto.gov/web/menu/search.html>.

Claim Objections

6. **Claim 9 is objected to because of the following informalities:** the article “a” should be placed between the terms “comprising” and “compound”. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. **Claims 1-2, 7-9, 16 and 19-20 are rejected under 35 U.S.C. 102(b)** as being anticipated by Kretz (U.S. Patent No. 6,110,719).

The claims are drawn to a composition comprising a buffer effective for maintaining a pH of aqueous composition at greater than or equal to about 6, and an organic anion of Formula I, wherein the instantly elected embodiment has the structure of Formula III, also known in the art as phytate or hexaphosphate.

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With respect to Claims 1-2, 7-8, 16, and 19-20, Kretz teaches a composition comprising sodium phytate in a Tris HCl buffer, pH 7.5 (column 3, lines 32-40).

With respect to Claim 9, Kretz teaches that the composition comprises the phytase enzyme (column 3, line 33); wherein the instant specification discloses that compositions suitable for being immobilized on a support include biomolecules such as proteins (pg 12, lines 10-13 and 23-25).

Thus, Kretz anticipates Claims 1-2, 7-9, 16 and 19-20.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. **Claims 1-2 and 7-21 are rejected under 35 U.S.C. 103(a)** as being unpatentable over Kreft et al (Eur. F. Physiol. 439(Suppl): R66-67, 2000) and Veraart et al (J. Chromatography A, 768: 307-313, 1997).

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Kreft et al teach nucleic acid hybridization compositions comprising nucleic acids, e.g. DNA, RNA, or mixtures thereof, the compositions further comprising an anionic surfactant SDS, inorganic phosphate and sodium phosphate, pH 7.0, and/or inorganic surfactants extant in Denhardt's Solution (Materials and Methods, pgs 66-67, joining ¶).

Kreft et al do not teach the composition(s) to comprise phytic acid; however, at the time of the invention, Veraart et al taught the use of phytic acid with a pH buffer comprising inorganic phosphate at pH 7.5 (pg 308, column 2, ¶2.4.1). Veraart et al taught that phytic acid is a large, polyionic molecule whose ionic strength is relatively large as compared with its concentration (pg 307, column 2, lines 7-11).

Veraart et al do not teach that phytic acid will be effective to substantially decrease ring formation upon drying of a spot less than or equal to about 300 micrometer diameter on a support, as recited in Claim 1. However, it is understood that the recited property is an inherent property of phytic acid, not a structural limitation, and thus the composition of Kreft et al, modified by including phytic acid as taught by Veraart et al, would have the recited effects.

It would have been obvious to one of ordinary skill in the art to modify the hybridization buffer of Kreft et al with the phytic acid of Veraart et al with a reasonable chance of success because the art recognized the growing popularity of phytic acid as a buffering agent (see Abstract, line 1). An artisan would be motivated to include phytic acid in a nucleic acid hybridization composition because phytic acid has a relatively large ionic strength as compared with its concentration (pg 307, column 2, lines 7-11), and the art recognizes that increasing ionic strength can reduce non-specific adsorption to a support (pg 307, column 1). The availability of twelve acidic groups with pKa values ranging from 1.9-9.5 provides the possibility to use phytic acid not only as an additive to suppress wall adsorption effects, but also to control the pH (pg 308, column 1, lines 4-8). Furthermore, the decreased adsorption properties afforded by phytic acid would increase the specific hybridization signal to noise ratio, and thus would be advantageous in hybridization assays.

Thus, Claims 1-2 and 7-21 are *prima facie* obvious.

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9. **Claims 1 and 14-15 are rejected under 35 U.S.C. 103(a)** as being unpatentable over Kretz (U.S. Patent No. 6,110,719) and Sambrook et al (Molecular Cloning: A Laboratory Manual, Second Edition, Cold Spring Harbor Laboratory Press, 1989).

The claims are drawn to a composition comprising a buffer effective for maintaining a pH of aqueous composition at greater than or equal to about 6, and an organic anion of Formula I, wherein the instantly elected embodiment has the structure of Formula III, also known in the art as phytate or hexaphosphate, wherein the buffer further comprises inorganic phosphate.

Kretz teaches a composition comprising sodium phytate in a Tris HCl buffer, pH 7.5 (column 3, lines 32-40). Kretz does not teach the composition to comprise inorganic phosphate; however, at the time of the invention, Sambrook et al taught how an artisan may create phosphate buffered solutions using sodium phosphate and/or potassium phosphate (pg B.21, Tables B.10 and B.11; see also pg B.12 for recipe).

It would have been obvious to one of ordinary skill in the art to modify the buffer of Kretz with the inorganic phosphate-providing buffer of Sambrook et al with a reasonable chance of success because Sambrook et al teach how to make a phosphate buffer with a buffering capacity at pH 7.5. An artisan would be motivated to substitute the Tris-HCl buffer of Kretz with the phosphate buffer of Sambrook et al because the phosphate buffer would provide a greater amount of inorganic phosphate groups into the composition and enhance the activity and buffering capacity of the phytic acid.

Thus, Claims 1 and 14-15 are *prima facie* obvious.

10. **Claims 42-45 are rejected under 35 U.S.C. 103(a)** as being unpatentable over Diehl et al (Nucleic Acids Research 30(16): e79, pgs 1-6, 2002) and Veraart et al (J. Chromatography A, 768: 307-313, 1997).

Diehl et al teach a method of forming spots of a composition on a surface, the method comprising a nucleic acid and a buffer effective for maintaining pH of aqueous composition equal to or about pH 7.5 (pg 2, column 1, ¶3). Diehl et al teach the method of spotting to comprise pin spotting machines (pg 2, column 1, ¶4).

Diehl et al do not teach the buffer to comprise phytic acid; however, at the time of the invention, Veraart et al taught the use of phytic acid with a pH buffer comprising inorganic phosphate at pH 7.5 (pg 308, column 2, ¶2.4.1). Veraart et al taught that phytic acid is a large, polyionic molecule whose ionic strength is relatively large as compared with its concentration (pg 307, column 2, lines 7-11).

Neither Diehl et al or Veraart et teach that the buffer, specifically comprising phytic acid, will be effective to substantially decrease ring formation upon drying of a spot less than or equal to about 300 micrometer diameter on a support, as recited in Claim 42. However, it is understood that the recited property is an inherent property of phytic acid, not a structural limitation, and thus the method and buffer of Diehl et al, modified by including phytic acid as taught by Veraart et al, would have the recited effect.

An artisan would be motivated to include phytic acid in a method of spotting organic compositions such as nucleic acids because phytic acid has a relatively large ionic strength as compared with its concentration (pg 307, column 2, lines 7-11), and the art recognizes that increasing ionic strength can reduce non-specific adsorption to a support (pg 307, column 1). The availability of twelve acidic groups with pKa values ranging from 1.9-9.5 provides the possibility to use phytic acid not only as an additive to suppress wall adsorption effects, but also to control the pH (pg 308, column 1, lines 4-8). Furthermore, large, polyionic molecules are preferable because they provide high ionic strengths at relatively low currents (pg 307, joining ¶). With relatively small ions used to enhance the ionic strength, the associated increment of the electric current is rather dramatic, resulting in the Joule heating effect. The Joule heating effect extant in piezoelectric delivery devices would be minimized in the presence of phytic acid, thus minimizing or avoiding unwanted heating of the composition that is to be deposited onto the support.

Thus, Claims 42-44 are *prima facie* obvious.

11. **Claims 42 and 45 are rejected under 35 U.S.C. 103(a)** as being unpatentable over the prior cited art as applied to Claim 42 above, and in further view of Lemieux et al (* of record in IDS).

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The prior cited art does not teach the method of forming spots, wherein the applying step comprises pin piezoelectric spotting.

However, at the time of the invention, Lemieux et al summarized DNA chip-making technologies, stating that one may produce microarrays by mechanical microspotting by pins (pg 281, column 2, ¶1) or by ink-jet nozzles that rely on the piezoelectric effect (pg 281, column 2, ¶4).

It would have been obvious to one of ordinary skill in the art to substitute pin spotting methods, as taught by Diehl et al, with spotting methods using the piezoelectric effect, as taught by Lemieux et al with a reasonable chance of success because the art recognized that such technology was available at the time. An artisan would be motivated to use piezoelectric spotting equipment, e.g. ink-jet, because the electric current can be precisely controlled, and thus the artisan can precisely control the amount of fluid that is taken up by the quill and dispensed onto the support, obtaining exceptional control of both quality and reproducibility.

Thus, Claims 42 and 45 are *prima facie* obvious.

12. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin K. Hill, Ph.D. whose telephone number is 571-272-8036. The examiner can normally be reached on Monday through Friday, between 9:00am-6:00pm EST.

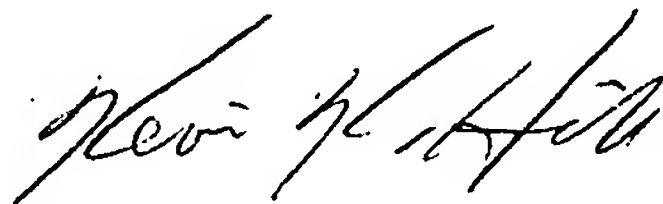
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph T. Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Q. JANICE LI, M.D.
PRIMARY EXAMINER

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read "Kevin J. Hill". The signature is written in a cursive, flowing style with a large initial "K".